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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,659	08/19/2003	Matthew O'Donnell	UOM 0276 PUSP	5262
22045 7590 04/10/2007 BROOKS KUSHMAN P.C. 1000 TOWN CENTER TWENTY-SECOND FLOOR SOUTHFIELD, MI 48075			EXAMINER KISH, JAMES M	
			ART UNIT	PAPER NUMBER
			3737	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/643,659

Applicant(s)

O'DONNELL ET AL.

Examiner

James Kish

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-9, 13-19, 21-26, 28-33, 37-43 and 45-52 is/are rejected.
- 7) ☒ Claim(s) 3, 10-12, 20, 27, 34-36 and 44 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 8/19/03 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Response to Arguments

Applicant's arguments filed December 4, 2006 have been fully considered but they are not persuasive.

1. Applicant has amended both independent claims 1 and 25 to more particularly point out and distinctly claim what the Applicants regard as their invention. Applicant argues that these amendments overcome the prior art of record. The Examiner respectfully disagrees.
2. With respect to the amendments, MacKinnon teaches a device that utilizes a laser to direct light energy into tissue to create a microbubble of gas or plasma (column 5, lines 65-67). Furthermore, MacKinnon teaches the use of an ultrasound crystal for generation of an ultrasonic pulse and detection of the returning echo signal (column 5, lines 46-54). Also included is the detection of an ultrasound pulse created when aforementioned microbubble collapses (column 6, lines 1-2). Sliwa discloses mapping fluid pressure information based on ultrasonic information gathered via ultrasound pulse wave interaction with microbubbles.
3. With respect to Applicant's arguments that there is no motivation to combine, Examiner sights page 3 of the Office Action dated September 20, 2007. Here it is stated that the combination would be obvious to use a laser, either in combination with or as an alternative to, an ultrasound emitter to case and acoustic wave associated with a microbubble to propagate in a volume of interest and be detected and analyzed to evaluate pressure of the surrounding environment in order to remove the need of

prefabricating microbubbles using polymers. By using a laser to create the microbubbles, which is taught by MacKinnon, it would remove a need for manufacturing polymeric microbubbles. This would reduce cost and the procedural step of injecting the polymeric microbubbles into the patient, thereby increasing the utility of the Sliwa device.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-2, 4-8, 17-18, 21-26, 28-32, 41-42 and 45-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sliwa, Jr. et al. (US Patent No. 5,749,364) in view of Mackinnon et al. (US Patent No. 6,546,272). Sliwa discloses a method of mapping fluid pressure information within a living body utilizing changes in acoustic behavior of microbubbles. It is also possible to use this information to assess the health of tissue (see Abstract). High frequency sound waves are applied to the region containing the microbubbles and an acoustic spectrum returned from the region (to a detector). A fluid pressure parameter is determined in response to at least one characteristic of the acoustic spectrum (column 3, lines 29-40). The pressure-related information is displayed in at least 2 dimensions (column 4, lines 56-63). Also, see

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column 3, line 65 through column 4, line 11 for discussion on evaluation of the health of bodily tissue. Sliwa uses an ultrasound transmitter to create the ultrasound wave. However, Mackinnon teaches an apparatus for in vivo imaging of internal organs. In one technique, a laser (with a focused beam; column 5, lines 33-35) is directed into tissue to create a microbubble of gas or plasma. When the bubble collapses, an ultrasound pulse is generated which is measured by a piezoelectric crystal detector (column 5, line 65 through column 6, line 2). Therefore, it was known in the art at the time the invention was made that a laser is capable of creating both microbubbles and ultrasonic waves that can be detected. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a laser, as taught by Mackinnon, either in combination with or as an alternative to an ultrasound emitter to cause an acoustic wave associated with a microbubble to propagate in a volume of interest and be detected and analyzed to evaluate pressure of the surrounding environment, as disclosed by Sliwa, in order to remove the need of prefabricating microbubbles using polymers (Sliwa: column 1, lines 37-42).

With regard to claims 21-22 and 45-46 see column 1, line 55 through column 2, line 10, as well as column 2, lines 31-35 of Sliwa.

With respect to claims 4 and 28, see column 6, lines 10-26 of Sliwa.

5. Claims 19 and 43 rejected under 35 U.S.C. 103(a) as being unpatentable over Sliwa, Jr. et al. in view of Mackinnon et al. as applied to claims 1-2, 4-8, 17-18, 21-26, 28-32, 41-42 and 45-52 above, and further in view of Esenaliev (US Patent No.

6,165,440). Sliwa in combination with Mackinnon teach the use of laser-induced microbubbles to create acoustic waves, which can be detected and analyzed, as described above. However, neither reference includes ultrafast pulses or additives. Esenaliev teaches interaction of electromagnetic pulses with nanoparticles for enhancement of drug delivery (see Abstract). The pulses can be on the level of short (nanoseconds) or ultrashort (picoseconds) as described at column 6, lines 40-44. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use ultrafast laser pulses with the additives described by Esenaliev in the system of Sliwa/Mackinnon because porous particles with gas-filled pores can substantially lower cavitation threshold because they already have initial bubbles, thereby (column 10, lines 22-35).

6. Claims 9, 13-16, 33, and 37-40 rejected under 35 U.S.C. 103(a) as being unpatentable over Sliwa, Jr. et al. in view of Mackinnon et al. as applied to claims 1-2, 4-8, 17-18, 21-26, 28-32, 41-42 and 45-52 above, and further in view of Baker, Jr. et al. (US Patent No. 6,471,968). Sliwa in combination with Mackinnon teach the use of laser-induced microbubbles to create acoustic waves, which can be detected and analyzed, as described above. However, neither reference includes nanodevices as part of an additive. Baker teaches a therapeutic and diagnostic array comprising nanodevices used for delivery of therapeutic agents (column 6, lines 49-67). For description of the device, see column 12. For therapeutic agents used with the device, see column 15. It would have been obvious to one having ordinary skill in the art at the

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time the invention was made to include the nanodevices as taught by Baker into the system of Sliwa/Mackinnon in order to actively determine time and location of the distribution of therapeutic agents and to monitor the response to therapy of a cell or tissue (see Abstract).

Allowable Subject Matter

7. Claims 3, 10-12, 20, 27, 34-36 and 44 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Kish whose telephone number is 571-272-5554. The examiner can normally be reached on 8:30 - 5:00 ~ Mon. - Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JMK


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